do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–3615 for ''Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip Bonforte, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1668, Silver Spring, MD 20993, 240–402–6980, email: *GenericDrugPolicy@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 22, 2017, FDA published a notice of public meeting with a 60-day comment period to request comments on the appropriate balance between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to innovator drugs. Interested persons were originally given until September 18, 2017, to comment.

Following publication of the June 22, 2017, notice of public meeting with request for comments, FDA received requests to allow interested persons additional time to comment. The requesters asserted that the time period of 60 days was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues.

FDA has considered the requests and is extending the comment period for the notice of public meeting until November 17, 2017.

Dated: September 14, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–19904 Filed 9–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0508]

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry entitled ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.'' This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA.

DATES: The announcement of the guidance is published in the **Federal Register** on September 19, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2009–D–0508 for ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Matthew Brenner, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised guidance for industry entitled ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.'' This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA. We are issuing this guidance consistent with our good guidance practices regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate given the upcoming compliance deadline for registration and listing for certain owners and operators of tobacco product manufacturing establishments. In addition, the compliance policy for certain product listing labeling submissions set forth in this revised guidance presents a less burdensome policy consistent with the public health (§ 10.115(g)(2)). Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation.

This revised guidance communicates a compliance policy for certain product listing labeling submissions. Specifically, FDA does not, at this time, intend to enforce the requirement that owners and operators of tobacco product establishments submit the labeling for each individually listed tobacco product if the registrant submits information that represents the labeling for a selected line of products. In deciding whether a registrant's submitted information falls within this compliance policy, FDA may consider whether the tobacco products' labeling is essentially identical (*e.g.,* the same formatting, fonts, colors, background text, and images) and whether the variations are limited to package size, nicotine strength, propylene glycol/vegetable glycerin ratio, and flavor. Under this compliance policy, a registrant could submit information that represents the labeling for a selected line of products, and FDA would not intend to enforce the requirements in subsections 905(i)(1)(A) and (B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 387e(1)(A) and (B)) with regard to labeling submissions.

This revised guidance also updates the compliance date for registration and listing for persons who owned or operated domestic manufacturing establishments engaged in the manufacture of newly deemed products prior to August 8, 2016, and continued to own or operate such establishment(s) on or after August 8, 2016. Such persons are required to register and submit product listing information under section 905 of the FD&C Act by December 31, 2016. However, in a guidance issued in May 2017, FDA announced that it does not intend to enforce these requirements with respect to newly deemed products provided the registration and product listing submissions are received by FDA on or before September 30, 2017.

The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in section 905 of the FD&C Act have been approved under OMB control number 0910–0650.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at either *https://www.regulations.gov* or *https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: September 14, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–19928 Filed 9–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–3998]

Flavor Developer and Manufacturer Site Tours Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is announcing an invitation for participation in its voluntary Flavor Developer and Manufacturer Site Tours Program. This program is intended to give CTP staff an opportunity to visit companies that develop and/or manufacture flavors (including flavor mixtures) that are sold to tobacco product manufacturers in order to gain a better understanding of the development, testing, and production of flavors and flavor mixtures used in the manufacturing of tobacco products. The site tours in this program are not intended as regulatory inspections. The purpose of this notice is to invite parties interested in participating in the Flavor Developer and Manufacturer Site Tours Program to submit requests to CTP.

DATES: Submit either an electronic or written request for participation in this program by November 20, 2017. See section IV of this document for information on requests for participation.

ADDRESSES: If your company is interested in offering a site visit, please submit a request either electronically to *https://www.regulations.gov* or in writing to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Karla Price, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by, among other things, adding a new chapter (chapter IX) granting FDA the authority to regulate tobacco product manufacturing, distribution, and marketing (Pub. L. 111–31). The Tobacco Control Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. On May 10, 2016, FDA published a final rule entitled ''Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products'' (81 FR 28974), which became effective on August 8, 2016. Under this rule, all products that meet the statutory definition of ''tobacco product'' set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), including components and parts, but excluding accessories of newly deemed products, are now subject to chapter IX of the FD&C Act.

CTP's Office of Science is conducting the Flavor Developer and Manufacturer Site Tours Program to provide its staff an opportunity to visit companies that develop and/or manufacture flavors (including flavor mixtures) that are sold to tobacco product manufacturers. Flavor developers and manufacturers are regulated by FDA if they, among other things, manufacture products that meet the statutory definition of a ''tobacco product'' set forth in section 201(rr) of the FD&C Act. The site tours will aid the Agency in gaining a better understanding of the development, testing, and production of flavors and flavor mixtures used in the manufacturing of tobacco products. The goal for the Flavor Developer and Manufacturer Site Tours Program is for CTP staff to gain firsthand exposure to how flavors are developed, tested, and produced.

II. Description of Flavor Developer and Manufacturer Site Tours Program

In the Flavor Developer and Manufacturer Site Tours Program, small groups of CTP staff will observe the operations of flavor developers and manufacturers, including the development, testing, and production of flavors that can be used by tobacco product manufacturers. The site tours in this program are not intended as regulatory inspections; rather, the program is meant to educate CTP staff and improve their understanding of flavors used in the manufacturing of tobacco products. It is anticipated that the site tours will take place in 2018.

III. Site Selection

CTP hopes to be able to tour small, medium, and large flavor developers and manufacturers, as well as companies that develop and/or manufacture flavors that are used for different categories of tobacco products (*e.g.,* cigarettes, cigars, smokeless tobacco, waterpipe tobacco, e-liquids). Final site selections will be based on the availability of funds and resources for the relevant fiscal year as well as the desire to visit a wide variety of flavor developers and manufacturers. All FDA travel expenses associated with the Flavor Developer and Manufacturer site tours will be the responsibility of FDA.

IV. Requests for Participation

To aid in site selection, your request for participation should include the following information:

- A description of your company, including the size of the organization;
- A list of the flavors your company develops and/or manufactures and the categories of tobacco product (*e.g.,* cigarettes, cigars, smokeless tobacco, waterpipe tobacco, e-liquids) for which your flavors are typically used;
- The physical address(es) of the site(s) for which you are submitting a request; and
- A proposed 1-day tour agenda.

Identify requests for participation with the docket number found in brackets in the heading of this document. Received requests are available for public examination in the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 14, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–19900 Filed 9–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as